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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,974	03/03/2004	Ray L. Pickup	10004227-9	4848

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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,974	PICKUP ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-100,102-120,123-128,131-136,140,141 and 145-150* is/are pending in the application.

4a) Of the above claim(s) *55-82,134,135 and 145-147* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-100,102-120,123-133,136,140,141 and 148-150* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, filed May 24, 2006, with respect to the rejection(s) of claim(s) 83-100, 108, 109, 119-122, 126-130, 136, 140, 141 and 148-150 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art references.

With respect to applicant's arguments regarding claims 105, 106 and 136, Applicant is reminded that the rejection of claims 105 and 106 is under 35 U.S.C. 103 in view of a secondary reference which was used by Examiner to remedy deficiencies in the teaching of Jacobsen. With respect to the rejection of claim 136, the rejection was inadvertently omitted from the Office action and is presented herein.

With respect to applicant's argument regarding the reliance by Examiner upon official notice with respect to the rejection of claims 123-135 and 131-133, Examiner agrees and withdraws the rejection, however a new grounds of rejection under 35 U.S.C. 103 is made in view of a newly found prior art reference.

With respect to applicant's arguments regarding the rejection of claims 102-107, specifically that there is no motivation to combine the teachings of Jacobsen and Hayes, Examiner disagrees. Claims 102-104 as previously presented set forth a jet dispenser (taught by Jacobsen) while claims 105-107 as previously presented and amended set forth an inkjet dispenser (taught by Hayes). A fluid jet dispenser is a jet dispenser, however Jacobsen did not teach a thermal droplet dispenser, a piezoelectric dispenser or a silicon electrostatic dispenser. Hayes taught an inkjet device that could be either a piezoelectric or an electromagnetic device.

An inkjet dispenser clearly a type of fluid jet dispenser, therefore Examiner disagrees with applicant's argument and maintains the rejections of claims 102-104 and 107. With respect to claims 105 and 106, the claims have been amended to successfully overcome a rejection under 35 U.S.C. 112, the amendment prompting new grounds of rejection in view of a newly found prior art reference.

Applicant's arguments with respect to the objection to claim 150 have been fully considered and are persuasive. The objection to claim 150 has been withdrawn.

Applicant's amendment to claims 91 and 105-107 have successfully overcome the rejection of those claims under 35 U.S.C. 112. Accordingly, the rejection of claims 91 and 105-107 has been withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 23, 2004 was noted in the previous action as considered by Examiner. The prior art references previously marked with a strikethrough are considered by Examiner as having been submitted with the parent application and a revised copy of the IDS is provided with this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 83 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the disclosure as originally filed for a droplet volume of less than or equal to 100 picoliters. References to prior art droplet volumes do not constitute support for the added limitation regarding droplet volume.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 83-100, 108, 109, 119-123, 126-130, 140, 141, and 148-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262).

With respect to **Claim 83:** Jacobsen teaches administering a drug cutaneously via a multipathway drug delivery device 20 comprising a fluid jet delivery pod 510 and drug containment pouch 506. (Col. 11, lines 50-52) The drug is expelled through aperture 522. (Col. 12, lines 1-5) Jacobsen teaches that the device is capable of administering daily delivery of a drug composition (Col. 5, lines 27-29), therefore the device is intended for prolonged contact with a cutaneous surface and capable of repeatedly dispensing a drug composition.

Jacobsen does not teach a droplet volume for the droplets of drug expelled through nozzle 522. Crivelli teaches an inkjet dispenser with a structure substantially identical to the device of Jacobsen, excepting the drug containment pouch. Crivelli teaches an ink droplet volume of 20 picoliters and teaches that a smaller orifice with a smaller cross-sectional area to

eject such droplets results in less aerosol generation, therefore it would be obvious to one of ordinary skill in the art to modify the droplet volume of drug expelled through nozzle 522 to be 20 picoliters or smaller as taught by Crivelli. Thus the combined teaching of Jacobsen and Crivelli satisfies the limitations of claim 83.

With respect to **Claim 84:** Jacobsen teaches that drug delivery device 20 is a patch. (Col. 5, lines 13-16)

With respect to **Claims 85,86,149:** Jacobsen teaches that device 20 has double-sided adhesion to prevent movement on a cutaneous surface after said patch 20 is applied, after which application, said device 20 is operatively connected to control pad 10 by communication cable 30 which actuates a drug administration program. (Col. 5, lines 13-55) Device 20 is encased in a foil wrapper prior to use, and Examiner asserts that this wrapper is capable of being reused to cover patch 20 again after a drug has been delivered to the absorbent sponge material in the patch to retain any drug composition amount present in said sponge material. (Col. 5, lines 55-61)

With respect to **Claim 87:** Bottom cap 536 seals pod 512 shut. Aperture 538 extends through the bottom cap for access by a hypodermic needle. A needle guard and seal 540 are positioned beneath the bottom cap and function to keep the needle end sealed and sterile until the seal is punctured upon a first propellant charge 526 actuated by control pad 10 for drug delivery from pouch 506. (Col. 12, lines 16-22, 31-48) Since the drug containment pouch 506 is disposed within pod 512, it is in prolonged contact with seal 540.

With respect to **Claims 88,91,98,148:** Jacobsen teaches administering a drug cutaneously via a multipathway drug delivery device 20 comprising a fluid jet delivery pod 510 and drug containment pouch 506. (Col. 11, lines 50-52) The drug is expelled through aperture 522. (Col. 12, lines 1-5) Jacobsen teaches that the device is capable of administering daily delivery of a drug composition (Col. 5, lines 27-29), therefore the device is intended for prolonged contact with a cutaneous surface and capable of repeatedly dispensing a drug composition.

With respect to **Claim 89,90,99,100,150:** Since Jacobsen teaches a pouch as a drug container and said pouch is collapsible and loose, the drug supply via pouch 506 is replenishable by supplying a new pouch 506 and placing said pouch with a predetermined unit dosage in said pod 512.

With respect to **Claim 92,93:** Jacobsen teaches that control pad 10 allows the user to program various frequencies of drug delivery, including dosages that enabled sustained levels of a drug through a maintenance delivery sequence and dosages administered at intervals. (Col. 5, lines 24-32, Col. 6, lines 45-50)

With respect to **Claim 94:** Jacobsen teaches that device 20 is capable of storing and mixing two separate drug composition components prior to delivery to a cutaneous surface. (Col. 13, lines 54-62)

With respect to **Claim 95,96:** Jacobsen teaches pod 580 having a first chamber 582 that is half full of a first drug component to be mixed with a second component. Said second drug component is stored in a second chamber 584 until it is ejected through a one-way valve 596

(interpreted herein as an orifice) to said first chamber 582 wherein it is mixed with said first component and the resulting composition is then capable of being delivered through patch 20. (Col. 13, lines 54-66, Col. 14, lines 1,2)

With respect to **Claim 97:** Since Jacobsen teaches that delivery device 20 is a patch and a drug delivery pod 580 capable of mixing two components of the same of different phases, Jacobsen is teaching that the component mixing is capable of occurring within a patch 20.

With respect to **Claim 108,109,118,126:** Jacobsen teaches that a drug is specifically selected by name via the ability of device 20 to read a label on a drug storage container as it is inserted. An external host interface 48 obtains and stores data via a wireless infrared reading device from a computer having microprocessor 40, said data including user ID, drug ID, dose and usage information. Wireless interface 48 then uses said data to monitor a patient's physiological status in tandem with sensors, this circuit also thus being capable of responding to the data by administering the appropriate dosage via device 20 according to the stored schedule data. (Col. 7, lines 24-38)

With respect to **Claim 119-120,127,128:** Please see the rejection of claim 108 in addition to the following: Jacobsen teaches using device 20 having interface 48 to administer stimulants, which would require monitoring of a patient's heartbeat and breathing (directly correlated to a change in activity level) as physiological parameters in order to function properly. (Col. 6, lines 32-35) This rejection of claims 121,122,129,130 is taking into account the rejection of those claims under 35 U.S.C 112.

With respect to **Claims 123,131:** Jacobsen teaches monitoring a physical parameter of a subject by using a monitor portion comprised of wireless interface 48 and sensors.

With respect to **Claim 140,141:** Jacobsen teaches that control pad 10 is responsible for sending electrical current to ignition wiring, which then ignites propellant gas, which expands the drug containment pouch so as to propel the drug in a gaseous state as a stream of droplets through nozzle 460 for delivery into the user's skin. Control pad 10 comprises a keypad 42 that is adapted for receiving input in the form of keystrokes from a user, which defines a manual triggering of control pad 10, the actuation device.

Claims 102-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262) as applied to claims 83-100, 108, 109, 119-123, 126-130, 140, 141, and 148-150 above, and further in view of Hayes et al (U.S. Patent No. 6,325,475).

With respect to **Claims 102-107:** Jacobsen teaches a fluid jet dispenser 450 but does not teach a particular type of fluid jet dispenser. Hayes teaches a jet dispenser for administering airborne materials into a user's nose that utilizes ink-jet technology. Hayes teaches that the transducer in the ink jet device can be piezoelectric or electromechanical, which encompasses thermal and silicon electrostatic transducers. ('475, Col. 7, lines 29-37) Since Hayes teaches that these are equivalent and all are suitable for use in an inkjet drug delivery device, it would be obvious to one of ordinary skill in the art to utilize any of piezoelectric, thermal or silicon electrostatic transducers as taught by Hayes.

Claims 124, 125, 132 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262) as applied to claims 83-100, 108, 109, 119-123, 126-130, 140, 141, and 148-150 above, and further in view of Meyerson et al (U.S. Patent No. 5,179,947).

With respect to **Claims 124,125,132,133:** Jacobsen teaches a plurality of sensors 60 for providing feedback regarding a patient's physiological status. Jacobsen does not teach any particular type of sensor. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore ti would be obvious to one of ordinary skill in the art to employ an accelerometer as the sensor of the device taught by Jacobsen so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

Claim 136 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262) as applied to claims 83-100, 108, 109, 119-123, 126-130, 140, 141, and 148-150 above, and further in view of Nakamura et al (U.S. Patent No. 6,564,092).

With respect to **Claim 136:** Jacobsen does not teach applying a bioactive composition attracting agent and pulling said bioactive toward said agent, or penetrating the agent with the

composition. Nakamura et al teaches that ointments (attracting agent) and patches are both known in the art as carriers or formats for delivering physiologically active (i.e. bioactive) compositions transdermally. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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